Department of Health and Human Services
Health Care Financing Administration
Operational Policy Letter 118
OPL2000.118

Date Issued: March 29, 2000

To:	**Current M+C Organizations**	**X**
	CHPP Demonstrations:	
	Evercare	**X**
	DoD (TriCare)	**X**
	SHMO I & II	**X**
	PACE	**X**
	M+C	**X**
	OFM Demonstrations:	
	MSHO	
	W.P.S.	
	HCPPs	**X**
	Federally Qualified HMOs	
	Section 1876 Cost Plans	**X**

Subject: Changes to Medicare Coverage Policies Affecting Medicare+Choice Organizations (M+CO)

Effective: January 1, 2000

Summary:

This operational policy letter reflects two changes made by the Medicare, Medicaid, and the State Children Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA): (1) extending the period of coverage for immunosuppressive drugs following an organ transplant and (2) imposing a moratorium on the $1,500 cap on outpatient therapy visits. In addition, the Health Care Financing Administration recently revised its coverage policies to allow Medicare coverage of adult liver transplantation to persons diagnosed with Hepatitis B. This operational policy letter describes how M+COs are to implement these coverage changes.

Q1. How are M+COs to handle coverage for immunosuppressive drugs?

A1. Section 227 of the BBRA extends Medicare benefits for immunosuppressive drugs following organ transplantation. Prior to this change, Medicare covered such drugs for 36 months after transplantation; effective January 1, 2000, for beneficiaries whose coverage expires in 2000, the program will cover these drugs for an additional 8 months in 2000, for a total of 44 months.
In future years, the specific number of months extended by this policy change may vary. The

extension will be determined by an estimate of how to best rationalize the remainder of the $150 million spending cap over the remaining years of the program (through fiscal year 2004).

Please note that this policy change does not affect Medicare eligibility for beneficiaries with end-stage renal disease. Beneficiaries with successful kidney transplantation continue to lose Medicare eligibility after 36 months unless they are eligible for Medicare as aged or disabled.

The law specifies that this policy change is to be treated as a National Coverage Determination (NCD) for 2000. Under section 1852(a)(5), when an NCD results in significant additional costs that are not reflected in payments to M+COs, M+COs are entitled to payment on a fee-for-service basis for the services covered as a result of the NCD. NCDs are defined as coverage decisions made by HCFA, and the term does not include a statutory change in Medicare coverage. Because Congress has provided that this change is to be treated as an NCD, however, M+COs are not expected to cover drugs during the time the beneficiary is in the 8-month extension period within their capitation payment. Such coverage should be billed separately using fee-for-service reimbursement mechanisms.

M+COs should hold these claims until January 1, 2001, because it will take until then to change our payment systems to allow claims submitted by M+COs for these services to be paid. Any claims submitted earlier will be rejected. Information on how to submit Medicare-compliant bills to the Fiscal Intermediaries and Carriers is available on the HCFA website at

www.hcfa.gov/medicare/edi/edi.htm
and
www.hcfa.gov/pubforms/p2192ch2.htm.

Starting in 2001, the Medicare+Choice (M+C) payment rates will include the costs associated with the coverage extension, so M+COs will be expected to cover the additional months of immunosuppressive drugs within their capitation payments. Adjusted community rate proposals and marketing materials for 2001 should reflect this change to the Medicare benefit package.

Q2. How are M+COs to handle the two-year moratorium on the $1,500 therapy cap?

A2. Section 221 of the BBRA provides a two-year moratorium on the annual $1,500 per beneficiary cap on Medicare spending for outpatient therapies that would otherwise have been implemented in 2000 under the Balanced Budget Act of 1997. As a result of this BBRA change, therapy will be covered that would not otherwise have been covered.

Because this change in statute is not a NCD subject to the provisions in section 1852(a)(5), and Congress has not in this instance directed us to treat this statutory change as a NCD as it did in the case of the immunosuppressive drug provision, M+COs are expected in 2000 to cover outpatient therapy exceeding the $1,500 cap (determined using original Medicare fee schedules) within their capitation payments.

Q3. How are M+COs to handle coverage of liver transplants for individuals diagnosed with Hepatitis B?

A3. Effective for services on or after December 8, 1999, section 35-53 of the Medicare Coverage Issues Manual extended Medicare coverage of adult liver transplantation to individuals diagnosed with Hepatitis B. This change is an NCD, and subject to section 1852(a)(5).

The regulations implementing section 1852(a)(5) are set forth at 42 C.F.R section 422.109. Section 422.109 specifies the circumstances under which Medicare will pay for coverage associated with an NCD using original Medicare (fee-for-service) mechanisms. First, the NCD must not already be accounted for in the M+C capitation amount. Second, the NCDs must be a "significant cost," meaning that the cost of the coverage change on an individual or aggregate level meets certain cost thresholds.

HCFA actuaries have determined that the NCD allowing liver transplants for beneficiaries with Hepatitis B does meet the first condition--it is not in the 2000 capitation rates--but does not meet the second condition. This NCD does not meet the significant cost thresholds for contract year 2000. Under the definition of significant cost in § 422.109(c), a cost is considered significant if either of two thresholds is met. The first is that the average cost of providing the service exceeds a specified amount. The second is that the aggregate cost nationwide represents at least 0.1 percent of the national standardized capitation rate multiplied by the total number of Medicare beneficiaries. Neither threshold is satisfied in the case of this NCD. In the case of the aggregate cost estimate, the actuaries' estimate was based primarily on the assumption that the shortage of livers for transplantation will severely limit increases in new transplants for beneficiaries with Hepatitis B in 2000.

Therefore, because this is not a significant cost NCD, no original Medicare (fee-for-service) payments will be made for liver transplants for M+CO enrollees with Hepatitis B in 2000. Because M+COs are required to follow Medicare coverage rules, M+COs must furnish liver transplants to individuals with Hepatitis B, should any such individuals present. These services must be provided within the 2000 capitation payment rates.

Starting in 2001, the update to the M+CO payment rates will reflect this coverage.

Contact: HCFA Regional Office Managed Care Staff

This OPL was prepared by the Center for Health Plans and Providers.